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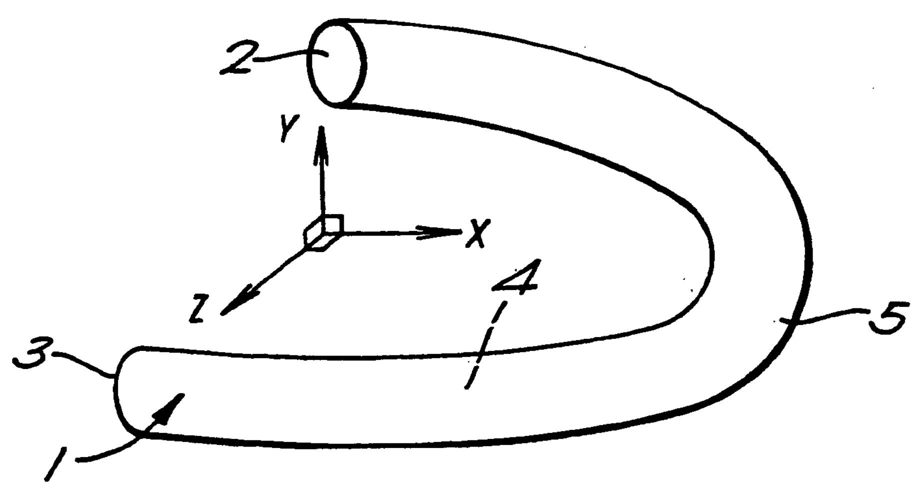
(54) Title: VASCULAR PROSTHESES

(57) Abstract

A vascular prosthesis comprising a length of generally hollow tubing having openings at both ends thereof and including at least one curved portion whose curvature extends within three dimensions of two mutually perpendicular planes such as to induce swirl flow in a liquid medium when such medium flows through said curved portion.



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VASCULAR PROSTHESES

The arterial system consists largely of curved and branching vessels. Arterial flow is generally laminar but is strongly influenced by inertial forces (Reynolds numbers >> 1). Almost all studies of arterial fluid dynamics consider the curvature and branching to be planar. The mechanics of steady flow (Reynolds number >> 1) in planar bends and branches are reasonably well understood and involve:

secondary motion in the plane of the bend or bifurcation; low wall shear at the inner wall of the bend (where flow separation may occur) and high wall shear at the outer wall; and low wall shear at the outer wall of a branch (where flow separation may occur) together with high wall shear at the inner wall (flow divider).

Several findings indicate that the local blood velocity field influences: (a) the dimensions and mechanical properties of vessels and the morphology, mechanics and metabolism of the endothelium (Yoshida et al, 1988), and (b) the development of vascular disease, in particular atherosclerosis (which causes heart attack and stroke) which develops preferentially in low shear regions in arteries (Yoshida et al, 1988); intimal hyperplasia (which causes the occlusion of vascular grafts) and which develops preferentially in low shear regions in side-to-side veno-arterial bypass grafts (Dobrin et al, 1988; Rittgers and Bhambhani, 1993), and thrombosis which occurs preferentially in low shear regions.

There has been limited consideration in the physiological literature of the mechanics of flow in non-planar bends and branches.

The aortic arch is recognised to curve three-dimensionally and rotational flow has been detected in the aortic arch and descending thoracic aorta (Caro et al, 1971;

Frazin et al, 1990).

The branching of the left common coronary artery is recognised to be non-planar and studies in a curved bifurcation model show skewing of the velocity profile away from the 'plane' of bifurcation, both upstream of the bifurcation and in a daughter tube (Batten and Nerem, 1982).

Studies of the velocity field in a realistic model of the abdominal aorta and aortic bifurcation show centrifugal effects caused by the curvature of the abdominal aorta and aortic bifurcation inducing helical flow structures and influencing the localisation of separation zones (Pedersen et al, 1992).

There has been study of the exact anatomical locations of atherosclerotic lesions and of the detailed flow patterns at these locations in transparent isolated human arteries (Asakura and Karino, 1990).

Recent model experiments by the present inventor led to an investigation as to whether non-planar curvature and branching may be more common than planar curvature and branching in the arterial tree.

With non-planar curvature and branching there is the expectation of skewing of the secondary motion (with the possible development of swirl flow) and alteration of the distribution of wall shear stress from that present with planar curvature and branching. The present inventor has undertaken several studies as a means of determining whether non-planar curvature and branching are common in the circulation. Inspection of a cast of a human aorta and of a rabbit aorta showed the origins of several branches of the aortic arch and abdominal aorta to be tangential to the axis of the parent vessel in more than one plane; non-planar curvature at some bifurcations, for example at the aortic bifurcation; and curvature of the inlet to some bifurcations in a plane other than the 'plane' of bifurcation, as at the lower abdominal aorta.

Phase-shift-based MRI studies have been undertaken with steady laminar flow in a planar model of the aortic bifurcation. When the inlet tube was straight, thin-slice dynamic flow imaging, sensitive to the axial component of the flow, shows the secondary motion in a daughter tube to be in the plane of bifurcation (see Figures 1 and 1A). When the inlet tube was curved in a plane normal to the plane of bifurcation, the secondary motion in the daughter tube was skewed (see Figures 2 and 2A).

Phase-shift-based MRI studies have also been undertaken on the lower abdominal aorta and aortic bifurcation in healthy human subjects. Cardiac gated projective phase contrast angiograms show the lower abdominal aorta and aortic bifurcation to be curved in a plane normal to the 'plane' of aortic bifurcation (concavity anterior) (Figs 3,4). Thin-slice dynamic flow imaging, sensitive to the axial component of the flow, shows skewing of the secondary motion in the common iliac arteries.

Other studies lead to the expectation that the velocity field at the carotid bifurcation is non-planar. Earlier MR studies in healthy human subjects showed the common carotid arteries to be curved in the antero-posterior plane (Caro et al, 1992). Anatomical studies show that the common carotid artery bifurcation does not lie in the antero-posterior plane.

Non-planar curvature and branching have been found to be relatively common in the arterial tree. Non-planar curvature and branching have been found to influence the blood velocity field and may therefore influence vessel biology and the development of vascular disease. From a limited knowledge of vascular bypass surgery, it appears that side-to-side anastomosis, as conventionally performed, involves the construction of a planar bifurcation/confluence (Dobrin et al, 1988; Eastcott, 1992). Side-to-Side anastomoses are prone to fail from intimal hyperplasia,

which is associated with low local blood velocity and possibly low local wall shear stress (Dobrin et al, 1988).

In the light of these various findings the present invention has been developed.

According to this invention there is provided a vascular prosthesis comprising a length of generally hollow tubing having openings at both ends thereof and including at least one curved portion whose curvature extends within three dimensions of two mutually perpendicular planes such as to induce swirl flow in a liquid medium when such medium flows through said curved portion.

In another aspect we provide a vascular prosthesis comprising at least one hollow body portion from which at least one branch member extends at an intersection between the body portion and said branch member, characterised in that said at least one branch member is of a shape and/or orientation with respect to the body portion such that at least part of said member extends in a non-planar configuration.

At least a section of the said at least one branch member may extend in a plane which is different from that plane of the body portion which includes the central axis of the body portion and the centre of said intersection between body portion and branch member.

Preferably a major part of the branch member may be curved so as to extend at an acute angle with respect to the body portion.

Preferred features of the invention are to be found in the sub claims.

In order that the invention may be illustrated and readily carried into effect, embodiments thereof will now be described by way of example only with reference to the accompanying drawings and wherein:

Figure 1 shows a phase-shifted magnetic resonance image (MRI) of a planar model of aortic bifurcation with

straight inlet, mapping the axial velocities in the daughter tube,

Figure 1A shows the physical form of the planar model of the aortic bifurcation which produced the image map shown in Figure 1,

Figure 2 shows a similar image map as in Figure 1, but wherein the inlet tube was curved perpendicularly to the plane of bifurcation, mapping axial velocities also in the daughter tube,

Figure 2A shows the physical form, including curvilinear variations thereof, of the non-planar model of the aortic bifurcation which produced the image map shown in Figure 2, and including primary tube 1 or curved tube 1c, daughter tubes 1A and 1B or when curved 1D,

Figure 3 shows a cardiac gated projective phase contrast thoracic aorta angiogram, right-left coronal view,

Figure 4 shows the posterior-anterior saggital view of the angiogram shown in Figure 3,

Figure 5 shows one embodiment of a prosthesis including a part helical section,

Figure 6 shows a further embodiment of a suitable prosthetic arterial or venous bypass, and

Figure 7 and 8 shows an alternative arrangement of prosthetic implant.

Referring to the drawings, the views of Figures 1 to 4 inclusive have already been identified and explained in the introduction hereto.

Figure 5 shows an embodiment of a prosthesis which comprises a length of generally hollow tubing 1 with openings 2,3 at each end which are adapted for surgical connection to a vein or artery by the provision of suitably shaped flanges. Blood from the circulatory system can flow from inlet 2 to outlet 3 along the hollow interior 4. The curved portion 5 is part helical in that the curvature extends within the X-Z horizontal plane and the mutually

perpendicular X-Y plane. Such non planar curvature induces a swirl to the flow to improve circulation and resist the formation of potentially damaging blockages within the interior. The tubing can be made of suitable bio-compatible material and such materials are commercially available and known to those skilled in the art. In order to maintain the tubing open and prevent collapse or kinking it is possible to use a stent or other structural support of plastic, metal or other material internally, externally or integral to the wall ~~of the~~ tubing.

In the Figure 6 arrangement, showing an arterial (or venous) bypass prosthesis in place, an artery 6 with internal blockage 7 is bypassed by means of a prosthesis according to the invention. The tubing 1 can be of similar shape, size and conformation as that shown in Figure 1, or the helical proportion can be even shorter in length e.g. less than one half of one turn or revolution. The inlet 2a and outlet 3a flanges have been surgically fastened by stitching to regions of the artery remote from the blockage. Swirl flow is induced by skewing of the blood flow within the non-planar curved portion 5, to improve flow characteristics and reduce the potential for deposit build up.

Figures 7 and 8 show different arrangements wherein a non planar curved branch member 8 extends from an opening in a hollow body portion 9, which latter may be inserted within a vein or artery either for receiving flow of blood from the said branch member, or for delivering a flow of blood thereto, wherein a swirl flow is established within the non-planar curved branch member.

Figure 9 shows one form of surgical connection between a prosthesis 1 having spirally curved portion 5 and a blood carrying vessel 7. The connection between the prosthetic tube 1 and vessel 7 is in the nature of an offset 'plumber's' joint, improving flow to or from the vessel,

wherein swirl flow is induced within the prosthesis.

Moreover, prosthetic devices according to the invention can include branching such as bifurcation. Indeed an example of a prosthesis is shown in Figure 2A, particularly including the curved portions 1C and/or 1D.

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CLAIMS

1. A vascular prosthesis comprising a length of generally hollow tubing having openings at both ends thereof and including at least one curved portion whose curvature extends within three dimensions of two mutually perpendicular planes such as to induce swirl flow in a liquid medium when such medium flows through said curved portion.

2. A prosthesis as claimed in claim 1 wherein the ends of the tubing are adapted to permit surgical connection to the vascular system.

3. A prosthesis as claimed in claim 1 or 2 wherein the curved portion is part helical in that the length of its curve is less than one complete turn.

4. A prosthesis as claimed in any preceding claim which is constructed from a resiliently flexible bio-compatible material.

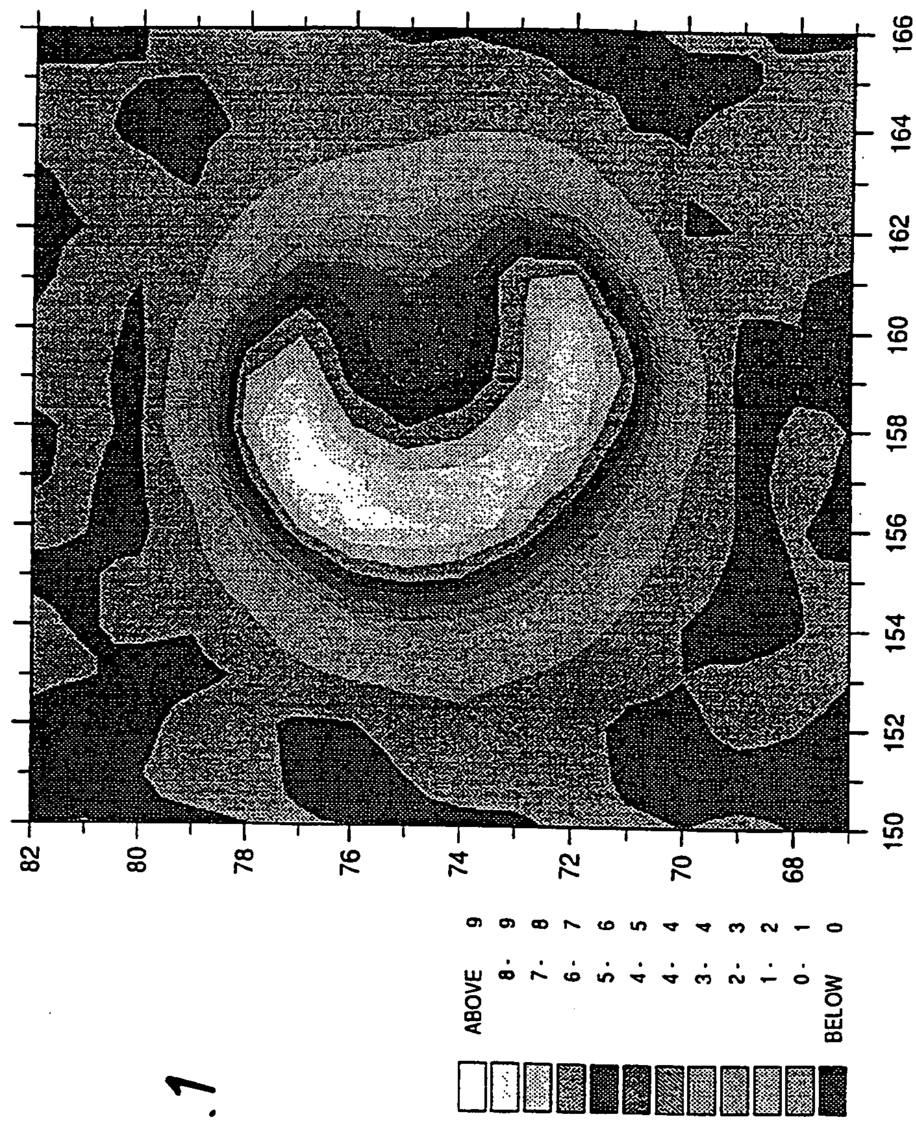
5. A vascular prosthesis comprising at least one hollow body portion from which at least one branch member extends at an intersection between the portion and said branch member, characterised in that said at least one branch member is of a shape and/or orientation with respect to the body portion such that at least part of said member extends in a non-planar configuration.

6. A vascular prosthesis as claimed in claim 5 wherein a section of the said at least one brand member extends in a plane which is different from that plane of the body portion which includes the central axis of the body portion and the centre of said intersection between body portion and branch

member.

7. A vascular prosthesis as claimed in claim 5 or 6 wherein a major part of the branch member may be curved so as to extend at an acute angle with respect to the body portion.

8. A vascular prosthesis as claimed in any preceding claim in combination with a vascular joining segment of generally tubular form having a hollow protuberance locatable within an end of said tubing or branch member.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0 - 1
BELOW 0

FIG. 1

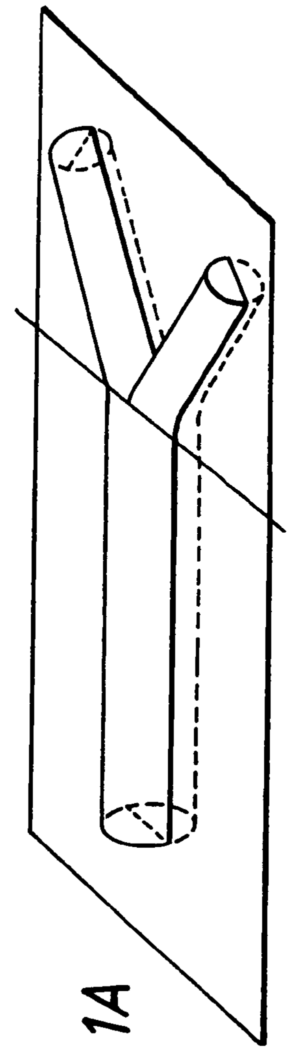
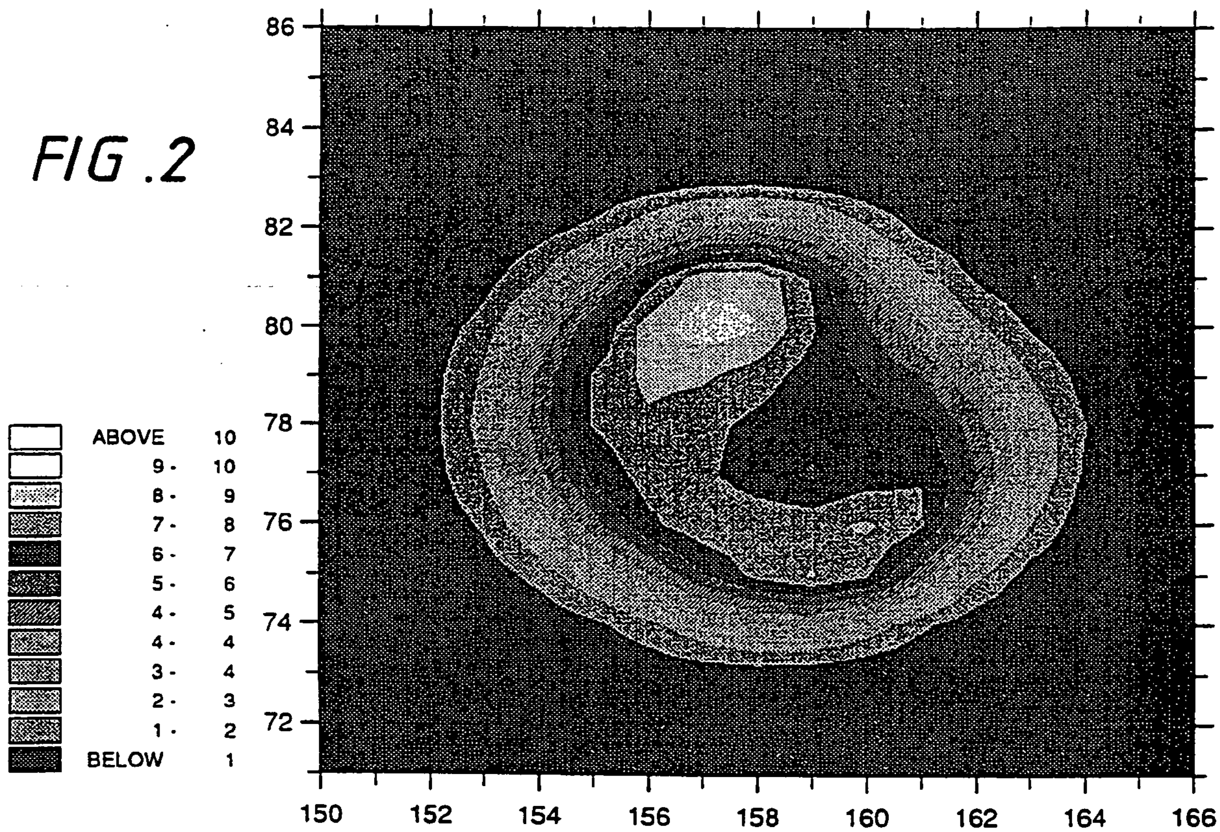


FIG. 1A

FIG. 2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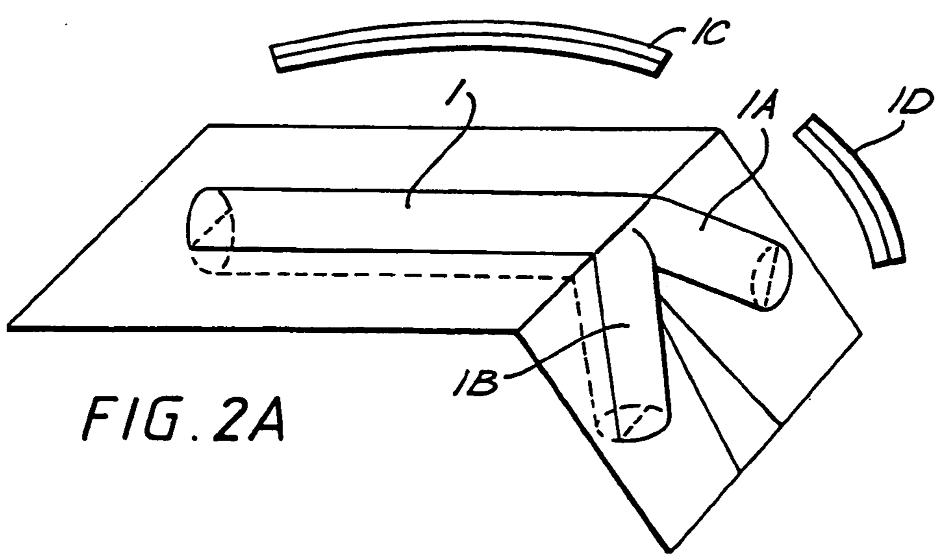
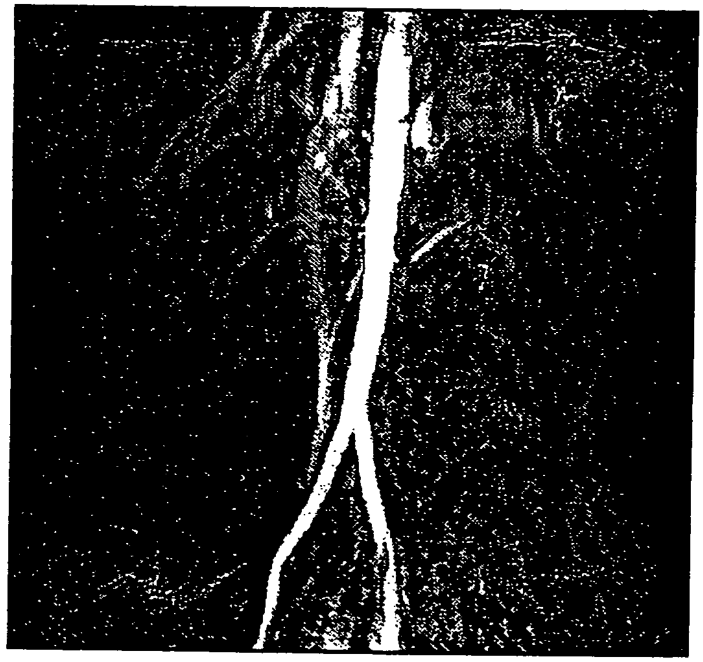

1C
1
1A
1D
1B

FIG. 2A

THORACIC AORTA

FIG. 3

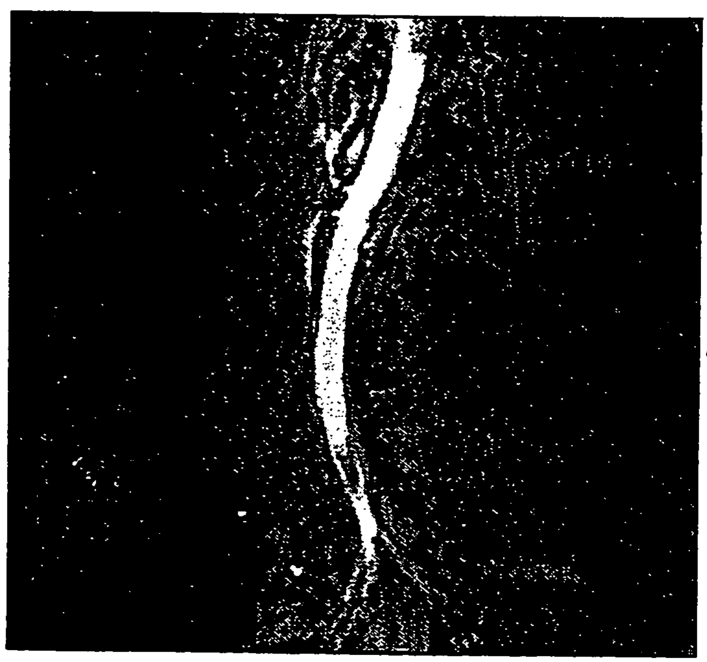
RIGHT



LEFT
CORONAL VIEW

FIG. 4

POSTERIOR



ANTERIOR
SAGGITAL VIEW

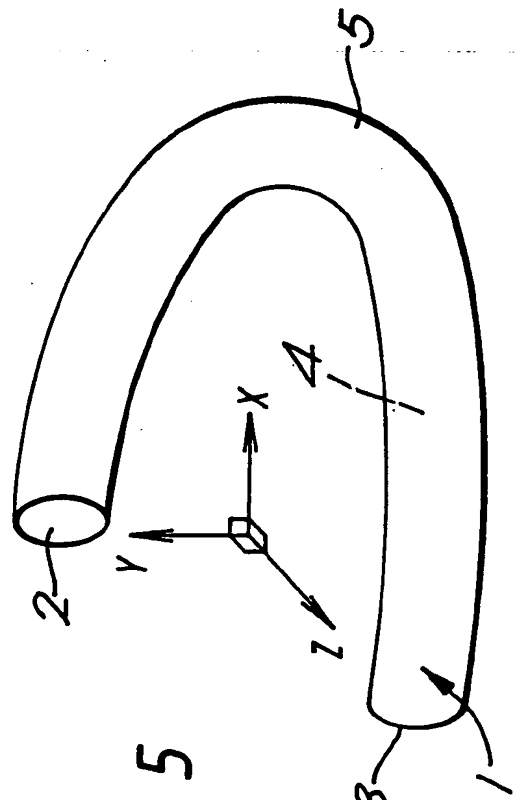


FIG. 5

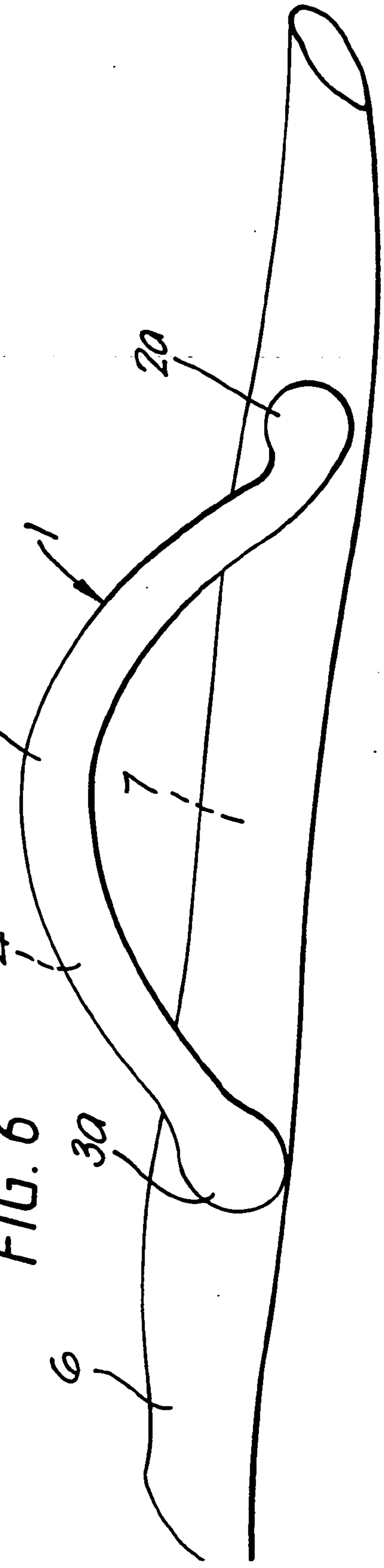


FIG. 6

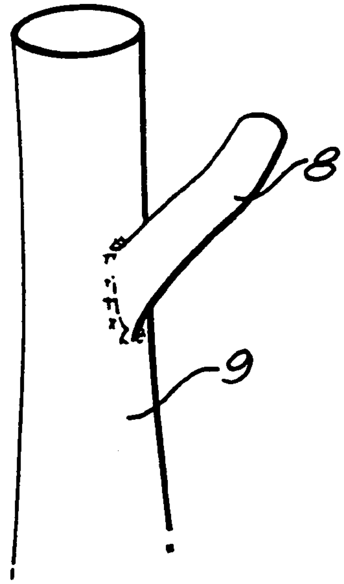


FIG. 7

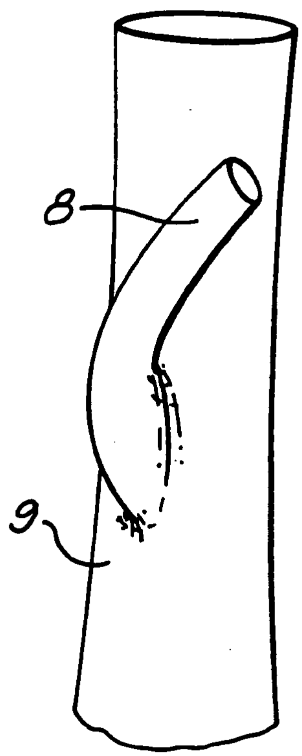
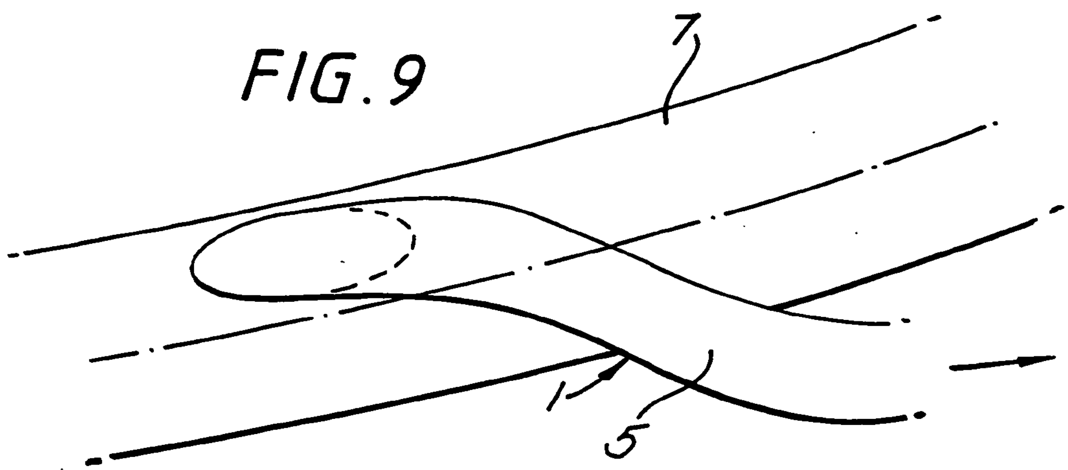


FIG. 8

FIG. 9



INTERNATIONAL SEARCH REPORT

International Application No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CIRCULATION, vol.82, no.6, December 1990, DALLAS TX,USA pages 1985 - 1994 L.J. FRAZIN ET AL. 'FUNCTIONAL CHIRAL ASYMMETRY IN DESCENDING THORACIC AORTA' cited in the application	1-4
Y	see page 1993, column 1, line 45 - column 2, line 2 cited in the application ---	5-8
Y	FR,A,2 666 502 (D. ROUX) 13 March 1992 see abstract; figure 1 see page 3, line 37 ---	5-7
Y	US,A,5 156 619 (W.K. EHRENFELD) 20 October 1992 see abstract; figures ---	8
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Date of the actual completion of the international search	Date of mailing of the international search report
24 November 1994	19.12.94

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International Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,4 938 740 (J. MELBIN) 3 July 1990 see column 5, line 10 - line 25; figure 4 ---	1
A	EP,A,0 503 101 (V.V. KESHELAVA) 16 September 1992 see column 4, line 41 - column 5, line 16; figures ---	1,2
A	US,A,4 313 231 (K. KOYAMADA) 2 February 1982 see the whole document ---	1,2,4,8
A	WO,A,93 02637 (NEWTEC VASCULAR PRODUCTS) 18 February 1993 ---	
A	US,A,5 139 515 (F.ROBICSEK) 18 August 1992 -----	

1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB 94/02023

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FR-A-2666502	13-03-92	NONE		
US-A-5156619	20-10-92	NONE		
US-A-4938740	03-07-90	US-A-	5104402	14-04-92
EP-A-0503101	16-09-92	JP-T-	4506765	26-11-92
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WO-A-9302637	18-02-93	AU-A-	2329892	02-03-93
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